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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/602,440	06/23/2000	Wilfried Fischer	2727-110	9975

20999 7590 05/20/2005

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/602,440	FISCHER ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Amendment under 37 C.F.R. §1.111 and Applicant's Arguments/Remarks, both filed 02/23/05 is acknowledged.

Claims 1 and 3-10 are pending. Claim 1 has been amended. Claim 2 has previously been cancelled. Claims 1 and 3-10 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman *et al.* (US Pat. No. 5,538,736).

Hoffman *et al.* teach an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties, wherein the active substance-containing plaster can also contain further additives, such as plasticizers (see reference column 1, lines 20-44), (column 3, lines 17-40); (column 5, lines1-35); (column 8, lines 11-16, 25-57). The active-substance containing plaster contains a back side, a skin side with a back layer, an active substance reservoir which can contain one or more active substances, a contact adhesive device on the skin side and optionally a detachable

cover layer, wherein the part of the active substance reservoir part that remains on the skin, has better adhesion to the skin than the back layer (abstract). Hoffmann teaches that apart from the basic materials, the plaster can also contain further suitable additives, such as solubilizers, softeners, plasticizers, tackifiers, stabilizers, fillers and enhancers (col. 8, lines 11-16). The plaster can be used as a transdermal therapeutic system for the controlled administration of medical active substances or also cosmetically active substances to human or animal skin (col. 1, lines 32-43). Figure 1 demonstrates a two-part adhesive active substance-containing reservoir wherein the adhesion of the first active substance reservoir part to the skin must be greater than the adhesion between the peel-off layer and the back layer (col. 4, lines 50-67 through col. 5, lines 1-9). The back layer can be permeable or impermeable and suitable materials for the production thereof are for example, polymeric substances, such as polyethylene and polypropylene. Permeable back layers are, for example, textile fabrics, such as non-woven fabrics, and the like (col. 8, lines 25-38). The detachable protective layer can be made detachable by applying a silicone layer. Other detachable protective layers are for example, polyvinylchloride, treated paper cellophane, etc. (col. 8, lines 45-53).

Hoffmann teaches an active substance-containing plaster for the release of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties. Hoffman does not teach that the layer of adhesive is rendered 'flowable' by the addition of a plasticizer. The phrase ' made flowable' is a future-intended use limitation that holds no patentable weight. Moreover, Hoffmann teaches a plaster comprising suitable additives, which include plasticizers (col. 8, lines 11-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to include various suitable additives,

particularly plasticizers, because they may serve to affect the bonding or flow properties of adhesion. The expected result would be an active substance-containing plaster for the release of medically active or cosmetically active substances to human or animal skin having distinct or different flowable adhesion properties, as similarly desired by the Applicant.

Claims 1 and 3-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori (US Pat. No. 5,695,779).

Mori teaches a release controlled transdermal therapeutic system comprising a rubbery adhesive, microcapsules comprising a water-soluble wall material and encapsulating drugs as a core material and a water-insoluble rubber- and rubber solvent-insoluble, water absorbing resin powder, the microcapsules and the resin powder being dispersed in the rubbery adhesive (see Abstract).

Mori, as seen in Figs. 3 and 4, teaches a patch type adhesive preparation wherein the adhesive is applied to a central portion of the base fabric (4) or the release paper (5) to form the adhesive layer (1) having the microcapsule (2) and the water absorbing resin powder (3) dispersed therein, and the adhesive layer (6) which does *not* contain the microcapsules is applied to the remaining portion, such as the circumferential portion of the base fabric (4), or the release paper (5). Alternatively, as seen in Figs. 5 and 6, the adhesive layer which does *not* contain the microcapsules is formed on the base fabric (4) or the release paper (5), and the adhesive layer containing the microcapsule (2) and the water absorbing resin powder (3) dispersed therein is laminated on the adhesive layer (6) (see reference column 6, line 47 – col. 7, line18).

According to Mori, the rubbery adhesive comprises a rubber adhesive component, a tackifier component and a plasticizer component (col. 3, lines 60-62). The rubbery adhesive component includes natural, isoprene, styrene, styrene-butadiene, silicone and acrylic rubbers, for example (col. 3, line 63 – col. 4, line 3). The tackifier component includes, for example, petroleum resins, hydrogenated resins, ester gums, isoprene resins and the like (col. 4, lines 4-15). The plasticizer component includes polybutenes, Vaseline, lanolin, liquid paraffin, higher fatty acid esters, vegetable and animal oils. The rubbery adhesives, tackifier and plasticizer components can be used alone or as a mixture of two or more kinds thereof.

The base fabric is woven fabrics or non-woven fabrics, such as polyvinyl chloride films, polyester films, polyolefin films, laminated films of polyvinyl chloride films and polyester films, polypropylene films or rayon films and films obtained by hot welding the non-woven fabrics on the polyester films or the like (col. 7, lines 32-37). The adhesives can be applied by any coating method, such as hot pressing method, hot melt method or solution coating. For the solution coating method, suitable solvents include toluene, n-hexane, isohexane, cyclohexane and a volatile oil for rubber (col. 7, lines 19-31).

Mori teaches patch type preparations comprising distinct adhesive layers whereby the microcapsules encapsulating drugs are contained in one area of the adhesive and are not contained or are excluded from the other adhesive area. The teachings of Mori demonstrate a transdermal preparation wherein the active agent is confined to only one area of the adhesive patch. Mori does not explicitly teach that the adhesive is 'made flowable' by a plasticizing additive. However, this is a future-intended use limitation, which without structural limitation affords no patentable weight. Moreover, since Mori explicitly teaches the use of plasticizers in

the adhesive preparation, the properties imparted by those plasticizers would also be the same as the properties desired by Applicant. The prior art teaches similar compositions comprising similar components, used in the same field of endeavor and to treat the same problems as that instantly desired. Hence, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 02/23/05 have been fully considered but they are not persuasive.

Firstly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 1 and 3-10 over Hoffman et al. (US 5,538,736) stating, "The two types of adhesives described in the instant invention both promote cohesion to the skin whereas the Hoffman plaster requires that at least one region of adhesive is detachable from the skin, but retains strong adhesion to the back layer of the plaster. Hoffman does not teach or suggest the advantage of spatially separating the two types of adhesives by addition of a plasticizing agent and does not teach that the presence or absence of a plasticizing agent could be used to improve adhesive properties of the patch, with the purpose of preventing the appearance of a 'dirty fringe' or to modulate the flow properties of the adhesive. Hoffman is silent regarding the change in adhesive properties afforded by the plasticizer. Hoffman does not teach or suggest that adhesives exhibit cold flow properties."

These arguments have been fully considered, but were not found to be persuasive. Hoffman *et al.*, as delineated above, teach an active substance-containing plaster for the release

of active substances to the skin comprising two different adhesives, each with distinct flowable adhesion properties. The active substance-containing plaster contains additives, such as plasticizers. Applicants' arguments were not found persuasive since the degree of adhesiveness has not been recited in the instant plaster. The absence of the recitation of degree of adhesion provided by the adhesive fails to overcome the teachings of the prior art. The instant claims as currently recited permit different adhesive forms. Moreover, in Hoffman, the adhesive does come into contact with the skin. Applicant's argument that 'Hoffman does not teach that the presence or absence of a plasticizing agent could be used to improve adhesive properties of the patch and that Hoffman is silent regarding the change in adhesive properties afforded by the plasticizer' is not persuasive since Hoffman teaches the inclusion of plasticizers. Since the use of the same component (*i.e.*, plasticizer) is provided in the plaster of Hoffman, the properties imparted by that component would also be the same. Moreover, it is not necessary that the prior art recognize a certain advantage attributable to a particular component, merely that the prior art teach the incorporation of that particular component in a related field of endeavor is sufficient. Furthermore, the selection of a known material based on its suitability for its intended use supports a *prima facie* case of obviousness. In the instant case, Hoffman teach the inclusion of plasticizers in their plaster, and thus the properties and advantages imparted by the plasticizers would be provided therein. The Examiner further notes, that Applicant's recitation of 'adhesive made flowable' in instant claim 1 is a future-intended use limitation and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963).

Secondly, Applicant argued regarding the 35 U.S.C. §103(a) rejection of claims 1 and 3-10 over Mori (US 5,695,779) stating, "Mori does not teach or suggest a patch with reduced cold flow properties. Mori does not describe regions of the patch that comprise regions of adhesives that are spatially separate by addition of a plasticizing component. Mori teaches away from the present invention by describing a transdermal system that comprises a plasticizer dispersed throughout the adhesive, and not confined to specific regions of the patch. Furthermore, Mori's transdermal system comprises additional ingredients, such as microcapsules and a water-insoluble rubber- and rubber solvent-insoluble water-absorbing resin, which can change the adhesive properties of the system."

These arguments have been fully considered, but were not found to be persuasive. Applicants' arguments were not persuasive since the degree of adhesiveness has not been recited in the instant plaster. The absence of the recitation of degree of adhesion provided by the adhesive fails to overcome the teachings of Mori. The instant claims as currently recited permit different adhesive forms. Mori teach the inclusion of plasticizers in the formulation, wherein the plasticizers would therefore provide for similar advantageous properties as that desired by Applicants. Applicant's argument that the 'transdermal system of Mori comprises additional ingredients, which can change the adhesive properties of the system' was not persuasive since the instant 'comprising' claim language permits the presence of additional components or ingredients asides from those recited in the formulation of Mori. Therefore, based on the

teachings of the prior art delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

H. N. Sheikh H.N.S.

Patent Examiner

Art Unit 1615

May 16, 2005

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SUPERVISORY PATENT EXAMINER
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